

### **REMARKS**

Claims 67, 69 and 97-107 are withdrawn. Claims 1-66 and 84 stand cancelled. Claims 68, 70-75, 78, 81-83 and 85-96 have been amended to address matters of formality and clarify the features of the invention. New claim 108 has been added; support therefore can be found in former claim 81 and elsewhere in the application. No new matter is added by virtue of the within amendments; support therefore can be throughout the specification and original claims.

Claims 78, 81, 82, 84 and 89 stand rejected under 35 USC §112, 2<sup>nd</sup> paragraph, for recitation of the terms "for example", ("e.g.") and "such as". The position is taken that such terms render the claims indefinite.

Each of the noted claims has been amended to remove the objectionable terms. Accordingly, withdrawal of the rejection is therefore proper.

Claims 67-96 stand rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1-3, 8-17, 22-29 and 34-37 of US Patent No. 6,713,089.

Applicant respectfully requests reconsideration of the rejection in view of the within amendments and remarks which follow. The opportunity to file a terminal disclaimer to overcome the rejection is acknowledged.

At the outset, it is noted that present independent claims 68 and 70 may be perceived, in part, as product-by-process claims. For example, as noted in the specification at page 22, line 33 – page 23, line 5, and page 23, line 24 – page 26, line 30, the conditions of step ii) are critical for the invention. Such conditions are presented as functional features in the claims for added certainty as to the scope of the Applicant's invention. The claimed features are not taught or even suggested by the cited art; nor would they be obvious to one skilled in the art facing the problem of providing a quick release pharmaceutical composition for oral administration of active substances with solubility and/or pKa values as claimed.

The remaining rejections are now discussed in combination for the sake of brevity.

Claims 67-72, 74-78 and 81-95 stand rejected under 35 USC §103(a) over Penkler et al., US Patent No. 5,854,226 (the '226 patent).

Claims 79-80 and 96 stand rejected under 35 USC §103(a) over the '226 patent and further in view of Skinhoj et al., US Patent No. 6,599,529 (the '529 patent) .

Claims 67-72, 74-78 and 81-95 stand rejected under 35 USC §103(a) over the '226 patent and further in view of Penkler, WO 95/32737 (the '737 publication).

Each of the rejections is traversed. The references cited, even in combination, do not teach or suggest the features of the claimed invention in any manner sufficient to sustain the rejections.

For instance, independent claim 68 and 70 each recite the following feature:

...the composition being in the form of a particulate composition or being based on a particulate composition which is obtained by contacting a powder comprising the therapeutically and/or prophylactically active substance with an aqueous medium in such a manner that the mean particle size of the particles of the particulate composition is at the most 100% larger than the mean particle size of the powder before contact with the aqueous medium, and ...

Consider this feature in view of the following three actions:

- i) An optional measurement of the mean particle size of the powder before contact with an aqueous medium.
- ii) Contacting the powder with an aqueous medium.
- iii) An optional measurement of the mean particle size of the powder after contact with an aqueous medium and drying.

Steps i) and iii) above serve to test whether step ii) has been properly conducted. In accordance with the present invention, it would not necessarily be required to perform steps i) and iii) on each and every production batch.

Applicant also notes the following differences between the present claims and the sieving described in the '226 patent. First, the '226 patent only teaches screening of the components NSAID and cyclodextrin, not of the whole composition. Second, the present claims do not require screening of the composition, nor of the active ingredient(s). In contrast, the screening method of the '226 patent appears to require that 100% of the screened material be passed through a sieve before further processing.

Further, the '226 patent does not teach conducting step ii) in a manner, such that "...the mean particle size of the particles of the particulate composition is at the most 100% larger than the mean particle size of the powder before contact with the aqueous medium...". According to the present invention, the conditions for contacting the powder with an aqueous medium are important, and not taught or suggested by the prior art.

Moreover, Applicant submits that one skilled in the art may set upon a research program varying a number of parameters in order to address the problem of the present invention. However, the cited art would not lead in the direction of the claimed invention (and solution to the problem thereby). Hence, the invention is not obvious.

With respect to the '529 patent, Applicant submits that such patent cannot be properly applied prior art against the present application since the '529 patent and the present application have a common inventor and are commonly assigned to Nycomed Danmark A/S.

Indeed, the subject matters of the '529 patent and the claimed invention were, at the time the claimed invention was made, owned by the same entity (Nycomed Danmark A/S) or subject to an obligation of assignment to that entity. Consequently, the '529 patent should be disqualified under §103(c) as 'prior art' under §103(a). See 35 U.S.C. 103(c)(1) and MPEP 706.02(I)(2).

Even beyond that, Applicant submits that the '529 patent cannot be properly applied under §103(a) since Applicant's invention was prior thereto. For instance, attention is directed to the '529 patent at column 6, lines 26 – 28, where it is stated: "...to obtain the first fraction (cf. Danish Patent Application filed on Sep. 10, 1998 in the name of Nycomed Danmark)."

Indeed, the '529 patent claims priority to an international application (PCT/DK98/00388) filed on September 10, 1998, which date coincides with the priority date of the present invention, i.e. the filing date of the Danish Patent Application mentioned above (Denmark PA 1998 01143, filed September 10, 1998).

Lastly, Applicant submits that it would not be obvious to combine the teachings of the '226 patent and the '737 publication and arrive at the present invention. For instance, the methods for making the products of the '226 patent and '737 publication are fundamentally different. Indeed, the '737 publication describes the formation of a paste by mixing powder with a wetting solution. Only post-factual hindsight would lead one skilled in the art to combine this technical methodology with the methodology of the '226 patent. Additionally, even assuming *arguendo* that one skilled in the art were to combine the teachings of these two documents, the combination would not lead to the presently claimed invention.

Accordingly, each of the §103(a) rejections is properly withdrawn. For example, it is well-known that to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference(s) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143.

There is no suggestion or motivation, either in the reference(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the cited reference(s) to make the claimed invention, nor is there a reasonable expectation of success.

In view of the above amendments and remarks, Applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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